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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 10/810,578      | 03/29/2004  | Hagit Eldar-Finkelman | 27457               | 2785             |

7590 03/15/2006  
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PRTSI INC.  
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ARLINGTON, VA 22215

EXAMINER

RUSSEL, JEFFREY E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1654

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/810,578 | <b>Applicant(s)</b><br>ELDAR-FINKELMAN, HAGIT |  |
|                              | <b>Examiner</b><br>Jeffrey E. Russel | <b>Art Unit</b><br>1654                       |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 7-9 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. Applicant's election of Group II in the response filed October 28, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3 and 4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Applicants' response filed October 28, 2005.

2. Claims 1, 2, and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite because of the use of the term "known substrate". It is not clear what constitutes a "known" substrate, e.g., a substrate which has been described once in a publication, or a substrate which is well-known to those of ordinary skill in the art. It is not clear if the term is limited to substrates which are identical to those known in the art, or if the term embraces obvious variations of those substrates which are known in the art. It is not clear if the term requires that the substrate per se must be known, or if the substrate must additionally be recognized as possessing the property of being a GSK-3 substrate. It is also not clear at what point in time it is to be determined whether or not a substrate is "known" or not, e.g. at the time the invention was made, at the time of patenting, or at the time of a potential act of infringement. The term is not defined in the specification.

3. The effective filing date of instant claims 1, 2, and 5-9 is deemed to be at least January 3, 2001, the filing date of parent application PCT/US01/00123. Claims 1, 2, and 5-9 are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent applications 09/951,902

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and PCT/US01/00123 because the parent applications, under the test of 35 U.S.C. 112, first paragraph, disclose the claimed invention.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 2, and 7-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Lu et al (U.S. Patent No. 6,495,376). Lu et al teach peptides identified as SEQ ID NOS:16, 28-30, and 32 (see column 29, Table 5), which have the same amino acid sequence as is recited in instant claim 1. The inhibitors of Lu et al, such as the peptide of SEQ ID NO:29 (see claim 5), can be combined with pharmaceutically acceptable excipients (see, e.g., column 14, line 64 - column 15, line 32). The peptides identified as SEQ ID NOS:16 and 28-30 have the same length as is recited in instant claim 2, and the peptide identified as SEQ ID NO:32 has the same amino acid sequence as is recited in instant claims 7 and 8. In view of the similarity in structure between the peptides of Lu et al and the peptide inhibitors claimed by Applicant, the peptides of Lu et al are deemed inherently to be capable of inhibiting the enzymatic activity of GSK-3 to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the peptides of Lu et al and Applicant's claimed peptide inhibitors to shift the burden to Applicant to provide evidence that the claimed peptide inhibitors are unobviously different than the peptides

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of Lu et al. Note also that intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

6. Claims 1 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by the Jicha et al article (J. Neurochemistry, Vol. 69, pages 2087-2095). The Jicha et al article teaches the peptide biotin-KKVAVVR phospho-TPPKSPSS in TBS (Tris-buffered saline). See page 2088, column 2, last paragraph. The peptide has the same amino acid sequence as is recited in instant claims 1, 7, and 8. In view of the similarity in structure between the peptide of the Jicha et al article and the peptide inhibitors claimed by Applicant, the peptide of the Jicha et al article is deemed inherently to be capable of inhibiting the enzymatic activity of GSK-3 to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the peptide of the Jicha et al article and Applicant's claimed peptide inhibitors to shift the burden to Applicant to provide evidence that the claimed peptide inhibitors are unobviously different than the peptide of the Jicha et al article. Note also that intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

7. Applicant's arguments filed February 21, 2006 have been fully considered but they are not persuasive.

The restriction requirement is maintained, and claims 3 and 4 remain nonelected, because the independent claim is not yet allowable. Note that should claims 3 and 4 be re-joined with the elected claims, the word "natural" in claim 3 will need to be addressed as it was in claim 1.

8. Comb et al (U.S. Patent No. 6,441,140) is cited as art of interest, being essentially duplicative of the references applied above, and teaching additional peptides (e.g., SEQ ID

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NOS:4, 5, 7, 11, 15, 21, and 22) which have the amino acid sequences recited in instant claims 1, 7, and 8.

9. Claims 5 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

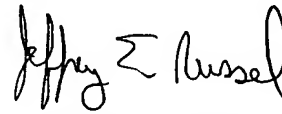
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is stylized with a large, looped "J" and "R".

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

March 13, 2006